DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 23, 2015

Mirada Medical, Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K143020
Trade/Device Name: LiverMultiScan
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: June 9, 2015
Received: June 10, 2015

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

FDA Indications for Use Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143020

Device Name
LiverMultiScan

Indications for Use *(Describe)*

LMS is indicated for use as magnetic resonance diagnostic device software application for non-invasive liver evaluation that enables the generation, display and review of 2D magnetic resonance medical image data and pixel maps for MR relaxation times.

LMS is designed to utilize DICOM 3.0 compliant magnetic resonance image datasets, acquired from Siemens MAGNETOM Skyra MR Scanners, to display the internal structure of the abdomen including the liver. Other physical parameters derived from the images may also be produced.

LMS provides a number of quantification tools such as rulers and region of interest to be used for the assessment of regions of an image to support existing clinical workflows.

These images and the physical parameters derived from the images, when interpreted by a trained physician, yield information that may assist in diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

LiverMultiScan 510(k) Summary

Date of summary:	10 May 2015
Submitter's name:	Mirada Medical Ltd
Submitter's address:	Oxford Centre for Innovation New Road Oxford Oxfordshire OX1 1BY United Kingdom
Submitter's contact:	Gwilym Owen
Telephone number:	+44 (0)1865 261410

Device Proprietary Name:	LiverMultiScan
Device Common Name(s):	LiverMultiScan**,** LMS
Classification Name:	Class II: Magnetic Resonance Imaging System (892.1000) Product Code: LNH

LiverMultiScan is Substantially Equivalent to the following Legally Marketed devices:

Predicate Devices

510(k) Number	Trade Name	Manufacturer
K141977	Software syngo MR E11A for the MAGNETOM systems Aera/Skyra	Siemens AG

Intended Use

LMS is indicated for use as magnetic resonance diagnostic device standalone software application for non-invasive liver evaluation that enables the generation, display and review of 2D magnetic resonance medical image data and pixel maps for MR relaxation times.

LMS is designed to utilize DICOM 3.0 compliant magnetic resonance image datasets to display the internal structure of the abdomen including the liver. Other physical parameters derived from the images may also be produced.

LMS provides a number of quantification tools such as rulers and region of interest to be used for the assessment of regions of an image to support existing clinical workflows.

These images and the physical parameters derived from the images, when interpreted by a trained physician, yield information that may assist in diagnosis.

Device Description

LiverMultiScan (LMS) is a standalone software application for displaying 2D Magnetic Resonance medical image data acquired from Siemens MAGNETOM Skyra MR Scanners. LMS runs on a workstation with color monitor, keyboard and mouse.

LMS is designed to allow the review of DICOM 3.0 compliant datasets stored on the workstation and the user may also create, display, print, store and distribute reports resulting from interpretation of the datasets.

LMS allows the display and comparison of combinations of magnetic resonance images and provides a number of tools for the quantification of magnetic resonance images, including the determination of triglyceride fat fraction in the liver.

LMS provides a number of tools such as rulers and circular region of interest to be used for the assessment of regions of an image to support a clinical workflow.

LMS allows users to create relaxometry parameter maps of the abdomen which can be used by clinicians to help determine different tissue characteristics to support a clinical workflow. Examples of such workflows include, but are not limited to, the evaluation of the presence or absence of liver fat.

LiverMultiScan (LMS) is intended to be used by trained healthcare professionals including, but not limited to, radiologists, gastroenterologists, hepatologists, radiographers and physicists.

LiverMultiScan is an aid to diagnosis. When interpreted by a trained physician, the results provide information, which may be used as an input into existing clinical procedures and diagnostic workflows.

LiverMultiScan offers:

- Advanced visualization of MR data
- Processing of MR data to quantify tissue characteristics including MR Relaxivity constants such as T2*, T1. cT1 and liver fat percentage
- Circular Region of interest statistics
- Snapshot of images to include in a report
- Report to include region statistics, snapshot images and user-entered text
- Export of snapshot images and report to storage
- Integration with Mirada DBx – a software module that maintains a local temporary cache of DICOM data and can interact with PACS, from which it can receive data

  Mirada DBx is a medical device data system (MDDS, product code OUG, regulation number 880.6310) used for DICOM connectivity with other systems.
- Ability to send data from Mirada DBx to PACS or other DICOM nodes for archive and distribution

Testing

LiverMultiScan is validated and verified against its user needs and intended use by the successful execution of planned performance, functional and algorithmic testing included in this submission. The results of performance, functional and algorithmic testing demonstrate that LiverMultiScan meets the user needs and requirements of the device, which are demonstrated to be substantially equivalent to those of the listed predicate devices.

Verification and Validation for LiverMultiScan has been carried out in compliance with the requirements of ISO 13485:2003, CFR 21 Part 820 and in adherence to the DICOM standard.

In conclusion, performance testing demonstrates that LiverMultiScan is substantially equivalent to, and performs at least as safely and effectively as the listed predicate device. LiverMultiScan meets requirements for safety and effectiveness and does not introduce any new potential safety risks.

Comparison to Predicate Devices

The proposed device is substantially equivalent to the predicate device image processing applications.

Although the proposed device does not contain software for image acquisition, the proposed device and predicate device support multi-slice MR data acquired using the same specific acquisition protocols, from the same scanner type and acquisition software to acquire the input data.

The proposed and predicate device include software applications which utilize MR data to visualize and enable quantify physiological characteristics in the liver to provide measurements which may be used to aid diagnosis.

The proposed device and both predicate device are software applications to facilitate the import and visualization of MR data sets.

Both the proposed device and the predicate device include applications to facilitate the import and visualization of MR data sets and include tools to enable the manipulation of the views and to enable the quantification and analysis of tissue characteristics in the liver from the MR data.

The proposed device and the predicate enable the quantification of analysis of tissue characteristics in the liver from the MR data.

The proposed device and the predicate device both support region of interest measurements derived from MR images and parametric maps of tissue characteristics.

The proposed device and predicate device facilitate the creation of a medical report containing the images and data analysis derived from quantification of liver tissue parameters.

The proposed device and predicate device reports all include tabular display of quantification statistics, parametric map images and include normal range references.

In conclusion, the proposed device (LiverMultiScan) does not result in any new potential safety risk and performs in accordance with its intended use as well as comparatively with the intended use of the chosen predicate.

We conclude that the LiverMultiScan device is as safe and effective as the predicate devices and poses no unanswered questions with regard to safety and efficacy.

The key similarities and differences are highlighted in the following summary table.

Device Comparison Table

Characteristic	LiverMultiScan	Software syngo MR E11A for the MAGNETOM systems Aera/Skyra
510(k) number	Not known	K141977
Classification	Class II. 892.1000 LNH	Class II. 892.1000 LNH
Intended Use	LMS is indicated for use as magnetic resonance diagnostic device software application for non-invasive liver evaluation that enables the generation, display and review of 2D magnetic resonance medical image data and pixel maps for MR relaxation times. LMS is designed to utilize DICOM 3.0 compliant magnetic resonance image datasets, acquired from Siemens MAGNETOM Skyra MR Scanners, to display the internal structure of the abdomen including the liver. Other physical parameters derived from the images may also be produced. LMS provides a number of quantification tools such as rulers and region of interest to be used for the assessment of regions of an image to support existing clinical workflows. These images and the physical parameters derived from the images, when interpreted by a trained physician, yield information that may assist in diagnosis.	The MAGNETOM systems [MAGNETOM Aera and MAGNETOM Skyra] are indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis. The MAGNETOM systems may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-Safe biopsy needles.
Device Description	LMS is a standalone software application for displaying 2D Magnetic Resonance medical image data acquired from Siemens MAGNETOM Skyra MR Scanners. LMS runs on a	The subject device, software syngo MR E11A for MAGNETOM Aera and MAGNETOM Skyra offers two new applications, LiverLab (an application of non-invasive liver evaluation) and MyoMaps (an application designed to provide a means to generate pixel maps for myocardial MR relaxation times). In addition,

Characteristic	LiverMultiScan	Software syngo MR E11A for the MAGNETOM systems Aera/Skyra
	workstation with color monitor, keyboard and mouse. LMS is designed to allow the review of DICOM 3.0 compliant datasets stored on the workstation and the user may also create, display, print, store and distribute reports resulting from interpretation of the datasets. LMS allows the display and comparison of combinations of magnetic resonance images and provides a number of tools for the quantification of magnetic resonance images, including the determination of triglyceride fat fraction in the liver. LMS provides a number of tools such as rulers and circular region of interest to be used for the assessment of regions of an image to support a clinical workflow. LMS allows users to create relaxometry parameter maps of the abdomen which can be used by clinicians to help determine different tissue characteristics to support a clinical workflow. Examples of such workflows include, but are not limited to, the evaluation of the presence or absence of liver fat.	software syngo MR E11A makes the Dot Cockpit available for the user to modify and create Siemens Dot Engine workflows in a very intuitive way which supplements some of the support of an application specialist. The software syngo MR E11A also includes new and modified sequences as well as minor modifications of already existing features. In addition, three additional coils are offered and some hardware components have been modified. Siemens Medical Solutions, USA Inc., intends to market MAGNETOM Aera and MAGNETOM Skyra with new software, syngo MR E11A. While syngo MR E11A offers additional capabilities with respect to the predicate device, the MAGNETOM Aera and MAGNETOM Skyra have the same technological characteristics as the predicate device (K121434; Cleared November, 5, 2012). Furthermore, Siemens Medical Solutions, USA Inc., intends to market a new configuration of the MAGNETOM Skyra with 24 receive channels with software syngo MR E11A. The MAGNETOM Aera and MAGNETOM Skyra will be offered ex-factory (new production) as well as in-field upgrades for the currently installed MAGNETOM Aera and MAGNETOM Skyra systems. The new MAGNETOM Skyra configuration with 24 receive channels will be offered as an ex-factory option (new production).
Indications for Use	LMS is indicated for use as magnetic resonance diagnostic device software application for non-invasive liver evaluation that enables the generation, display and review of 2D magnetic resonance medical image data and pixel maps for MR relaxation times. LMS is designed to utilize DICOM 3.0 compliant magnetic	The MAGNETOM systems [MAGNETOM Aera and MAGNETOM Skyra] are indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be

Characteristic	LiverMultiScan	Software syngo MR E11A for the MAGNETOM systems Aera/Skyra
	resonance image datasets, acquired from Siemens MAGNETOM Skyra MR Scanners, to display the internal structure of the abdomen including the liver. Other physical parameters derived from the images may also be produced. LMS provides a number of quantification tools such as rulers and region of interest to be used for the assessment of regions of an image to support existing clinical workflows. These images and the physical parameters derived from the images, when interpreted by a trained physician, yield information that may assist in diagnosis.	produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis. The MAGNETOM systems may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-Safe biopsy needles.
Target Population	Any patient type who is suitable for an MRI scan	Any patient type who is suitable for an MRI scan
Where used	Clinical/Hospital Environment	Clinical/Hospital Environment
Anatomical Site	Abdomen, Liver	Abdomen, Liver, Heart, various other anatomical sites
Energy Used and/or Delivered	None – software only application. The software application does not deliver or depend on energy delivered to or from patients	When used in conjunction with MAGNETOM MR Scanners, the scanner delivers electromagnetic energy. The software applications do not deliver or depend on energy delivered to or from patients
Human factors	Designed to be used by trained clinicians	Designed to be used by trained clinicians
Design Purpose	Standalone software application to facilitate the import and visualization of MR data sets encompassing the abdomen, including the liver with functionality independent of the MRI equipment vendor	Software tool used as an accessory to an MR scanning machine, to facilitate the import and visualization of multi-slice, spin-echo MR data sets. Includes an application for visualization of Cardiac MR datasets and an application for MR datasets encompassing the abdomen for visualization of the Liver
Design: Data visualization	Software application intended to display and visualize 2D multi-slice, spin-echo MR data sets encompassing the abdomen. The user may process, and review DICOM 3.0 compliant datasets within the system and/or across computer networks	software application for visualization of DICOM 3.0 compliant multi-slice, spin-echo MR data sets encompassing the abdomen and chest
Design: MR relaxometry	T1, cT1 & T2* Mapping	T1, T2 & T2* Mapping

Characteristic	LiverMultiScan	Software syngo MR E11A for the MAGNETOM systems Aera/Skyra
mapping		
Design: Liver Fat quantification	Utilizes magnetic resonance images that exploit the difference in resonance frequencies between hydrogen nuclei in water and triglyceride fat using DIXON method	Utilizes magnetic resonance images that exploit the difference in resonance frequencies between hydrogen nuclei in water and triglyceride fat using DIXON method
Design: Region of Interest measurements	Mean, Median, Standard deviation, Interquartile range measurements created from a cross sectional slice of liver tissue	Mean, Standard deviation, Histogram.
Design: Supported modalities	DICOM 3.0 compliant MR data from GRE Echo & Molli acquisition protocols.	DICOM 3.0 compliant MR data from GRE Echo & Molli acquisition protocols.
Design: Reporting	Liver quantification images and analysis collated in a report.	Liver quantification images and analysis collated in a report. Cardiac quantification images and analysis collated in a report
Performance	Validated with volunteer and phantom scans	Validated with volunteer and phantom scans and synthetic raw data
Standards met	IEC 62304, DICOM 3.0	IEC 62304, DICOM 3.0
Materials	Software product only	Not applicable to software component of this device.
Biocompatibility	N/A, Software product only	N/A, Not applicable to software component of this device.
Compatibility with the environment and other devices	Compatible with data from Siemens Skyra 3T MR scanners. Compatible with Microsoft windows	Compatible with data from Siemens Aera 1.5T & Skyra 3T MR scanners Compatible with Microsoft windows
Sterility	N/A, Software product only	Not applicable to software component of this device.
Electrical Safety	N/A, Software product only	Not applicable to software component of this device.
Mechanical Safety	N/A, Software product only	Not applicable to software component of this device.
Chemical Safety	N/A, Software product only	Not applicable to software component of this device.
Thermal Safety	N/A, Software product only	Not applicable to software component of this device.
Radiation Safety	N/A, Software product only	Not applicable to software component of this device.
Operating System	Microsoft Windows	Microsoft Windows

Conclusion

In conclusion, the proposed device (LiverMultiScan) does not result in any new potential safety risk and performs in accordance with its intended use as well as comparatively with the intended use of the chosen predicates.

We conclude that the LiverMultiScan device is as safe and effective as the predicate devices and poses no unanswered questions with regard to safety and efficacy.